Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2150315	(X3) Date Survey Completed 09/13/2024
Name of Provider or Supplier Madison Medical Affiliates, Inc	**Street Address, City, State** 12831 N Port Washington Rd, Mequon, WI	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the regional director, staff A, the laboratory did not verify the accuracy of potassium hydroxide (KOH) testing for two of two events in 2023. Findings include: 1. Review of laboratory records showed no evidence of twice annual accuracy checks of KOH testing in 2023. 2. Interview with the staff A on September 13, 2024, at 11:25 AM confirmed the laboratory had not verified the accuracy of the KOH test twice annually in 2023.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation of reagents, review of laboratory records and interview with the regional director, staff A, the laboratory used expired reagents to perform potassium hydroxide (KOH) testing for eleven of thirteen patients tested in 2024. Findings include: 1. Observation of KOH reagent on September 13, 2024, at 11:05 AM showed 10 vials of Microbiologics KOH 10% 2.4 milliliter bottles, Lot# 23032302, expiration date 01/31/2024, available for patient testing 2. Review of patient testing logs showed

	eleven KOH patient tests had been performed between February 1, 2024 and August 20, 2024. 3. Interview with the staff A on September 13, 2024, at 11:15 AM confirmed the laboratory used expired reagents to perform KOH testing.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on surveyor review of testing personnel competency records and laboratory records and interview with the regional director, staff A, the technical consultant did not perform a semiannual evaluation of the performance for one of one new testing personnel during the first year the individual performed patient testing. Findings include: 1. Review of testing personnel competency records for staff B showed initial competency on September 12, 2023, for potassium hydroxide (KOH) testing. Further review showed no documentation of a semiannual competency evaluation. 2. Review of the KOH patient testing log showed staff B had performed KOH testing between September 12, 2023 and September 13, 2024. 3. Interview with staff A on September 13, 2024, at 10:08 AM confirmed the technical consultant did not perform a semiannual evaluation of the performance for one of one new testing personnel during the first year the individual performed patient testing.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on surveyor review of new employee training records and interview with the regional director, staff A, the technical supervisor did not document initial training and competency for one of one new testing personnel who performs high complexity testing in the Mohs laboratory. Finding include: 1. Review of new employee training records showed no documentation of initial training and competency for staff C. 2. Interview with staff A on September 13, 2024, at 10:08 AM confirmed staff C had performed high complexity laboratory testing and the technical supervisor did not document initial training and competency for testing personnel.